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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,755	01/30/2004	Patricia Ann Piers	2479-23	7087

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EXAMINER	
STULTZ, JESSICA T	
ART UNIT	**PAPER NUMBER**
2873	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,755	PIERS ET AL.	
	Examiner	Art Unit	
	Jessica T. Stultz	2873	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-81 and 83-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-81 and 83-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/027,703.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner's Comments

For applicant's information, the abstract filed February 24, 2005 overcomes the previous objection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 67-73 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Roffman et al.

Regarding claim 67, Roffman et al discloses an intraocular correction lens (Column 1, line 57-Column 2, line 2 and Column 5, lines 6-12, wherein the lens is an intraocular lens) having at least one aspheric surface (Column 5, lines 13-17, wherein the lens surfaces are aspheric) which when its aberrations are expressed as a linear combination of polynomial terms (Column 1, lines 47-56, wherein the aberrations are described as Zernike polynomials), is capable of, in combination with a lens in the capsular bag of an eye reducing similar such aberration terms obtained in a wavefront having passed the cornea (Column 2, line 47-Column 2, line 56 and Column 5, lines 13-17, wherein the lens is an intraocular lens, and therefore interacts with the capsular bag of the eye and reduces wavefront aberration), thereby obtaining an eye

sufficiently free from aberrations (Abstract and Column 1, lines 47-56, wherein the lens corrects for high order aberrations).

Regarding claims 68-69, Roffman et al further discloses that the aspheric surface is the anterior or posterior surface of the lens (Column 5, lines 6-17, wherein any of the lens surfaces are aspheric).

Regarding claim 70, Roffman et al further discloses that the polynomial terms are Zernike polynomials (Column 1, lines 47-56, wherein the aberrations are described as Zernike polynomials).

Regarding claim 71, Roffman et al further discloses that the lens is capable of reducing polynomial terms representing spherical aberrations and astigmatism (Column 1, lines 47-56, wherein the lens corrects for spherical aberrations and astigmatism).

Regarding claim 72, Roffman et al further discloses that the lens is capable of reducing the 11^{th} Zernike polynomial term of the 4^{th} order (Column 1, lines 47-56, wherein the lens corrects for spherical aberrations, i.e. the 11^{th} Zernike polynomial of the 4^{th} order).

Regarding claims 73 and 76, Roffman et al further discloses that the lens is made from a soft or rigid biocompatible material (Column 3, lines 32-43 and Column 4, lines 57-63, wherein the lens is either a soft or hard lens).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74-75, 77-81, and 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roffman et al in view of Callahan et al.

Regarding claim 79, Roffman et al discloses an intraocular lens as shown above, but does not specifically disclose a method of improving the visual quality of the eye by implanting the intraocular correction lens. Callahan et al teaches of implanting an intraocular lens (Column 7, lines 21-37, wherein the implantation method is disclosed) for the purpose of providing optical correction to the eye wherein the lens remains in a fixed position within the eye (Column 4, lines 41-45). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the lens of Roffman et al to further include a method of improving the visual quality of the eye by implanting the intraocular correction lens since Callahan et al teaches of implanting an intraocular lens for the purpose of providing optical correction to the eye wherein the lens remains in a fixed position within the eye.

Regarding claims 74-75 and 85, Roffman et al discloses an intraocular lens as shown above, but does not specifically disclose that the lens is made of silicone or a hydrogel. Callahan et al teaches of an intraocular lens made of silicone or hydrogel for the purpose of using a material that is easy to deform by compression, rolling, folding, stretching for insertion into the eye through a small incision (Column 5, lines 24-39, wherein the haptic is made of silicone or hydrogel). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the intraocular lens of Roffman et al to be made of silicon or hydrogel since Callahan et al teaches of an intraocular lens made of silicone or hydrogel for the purpose of using a material that is easy to deform by compression, rolling, folding, stretching for insertion into the eye through a small incision.

Regarding claims 77-78 and 83, Roffman et al discloses an intraocular lens as shown above, but does not specifically disclose that the lens be adapted to be implanted in the posterior chamber bag comprising a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining the optical part in the central location, the optical part and the support element together having a concave posterior surface which is part of a non-spherical surface, the intersection between the non-spherical surface and any plane containing the optical axis representing a flawless curve free from discontinuities and points of inflection or that the lens is adapted to be implanted in the anterior chamber of the eye and fixated to the iris. Callahan et al teaches of an intraocular lens adapted to be implanted in the posterior chamber bag (Column 6, line 60-Column 7, line 45, wherein the intraocular lens "10" is implanted into the posterior chamber, Figure 4) comprising a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining the optical part in the central location (Column 6, line 60-Column 7, line 45 and Column 4, lines 41-45, wherein the optical part is optic "20", the supporting elements are haptics "30" which hold the optic in the centered on the eye, Figure 4), the optical part and the support element together having a concave posterior surface which is part of a non-spherical surface (Shown in Figure 4, wherein the surface is concave and non-spherical), the intersection between the non-spherical surface and any plane containing the optical axis representing a flawless curve free from discontinuities and points of inflection (Shown in Figure 4) and that the lens is adapted to be implanted in the anterior chamber of the eye and fixated to the iris (Column 5, line 11-Column 6, line 59, wherein the lens is implanted into the anterior chamber of the eye, Figure 1) for the purpose of providing optical

correction to the eye wherein the lens remains in a fixed position within the eye (Column 4, lines 41-45). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the lens of Roffman et al to further be adapted to implanted in the posterior chamber bag comprising a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining the optical part in the central location, the optical part and the support element together having a concave posterior surface which is part of a non-spherical surface, the intersection between the non-spherical surface and any plane containing the optical axis representing a flawless curve free from discontinuities and points of inflection or that the lens is adapted to be implanted in the anterior chamber of the eye and fixated to the iris since Callahan et al teaches of an intraocular lens adapted to be implanted in the posterior chamber bag comprising a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining the optical part in the central location, the optical part and the support element together having a concave posterior surface which is part of a non-spherical surface, the intersection between the non-spherical surface and any plane containing the optical axis representing a flawless curve free from discontinuities and points of inflection and that the lens is adapted to be implanted in the anterior chamber of the eye and fixated to the iris for the purpose of providing optical correction to the eye wherein the lens remains in a fixed position within the eye.

Regarding claims 84 and 86, Roffman et al further discloses that the lens is made from a soft or rigid biocompatible material (Column 3, lines 32-43 and Column 4, lines 57-63, wherein the lens is either a soft or hard lens).

Regarding claim 80, Roffman et al and Callahan et al disclose and teach of a method for improving the visual quality of an eye, but do not specifically disclose that spectacles or correction lenses are provided outside the eye to further improve the visual quality. However, it is well known in the art of optical corrective lenses for patients to use spectacles in addition to other optical corrective means for the purpose of providing correction of additional problems such as macular degeneration, color blindness, or to block UV rays. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the method for improving the visual quality of an eye of Roffman et al and Callahan et al to further include spectacles or correction lenses provided outside the eye to further improve the visual quality since it is well known in the art of optical corrective lenses for patients to use spectacles in addition to other optical corrective means for the purpose of providing correction of additional problems such as macular degeneration, color blindness, or to block UV rays.

Regarding claim 81, Roffman et al and Callahan et al disclose and teach of a method for improving the visual quality of an eye, but do not specifically disclose that the cornea of the patient receiving the intraocular correction lens has been modified by means of a laser. However, it is inherent from Callahan et al that the cornea of the patient has been modified by a laser, this being reasonably based upon a small incision being made in the cornea prior to insertion of the intraocular lens for the purpose of placing the haptics of the lens into the incision (Column 7, lines 21-37). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the method for improving the visual quality of an eye of Roffman et al and Callahan et al to further include modifying the cornea of the patient receiving the intraocular correction lens by means of a laser since it is inherent from Callahan et al that the

cornea of the patient has been modified by a laser, this being reasonably based upon a small incision being made in the cornea prior to insertion of the intraocular lens for the purpose of placing the haptics of the lens into the incision.

Claims 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roffman et al in view of Chipman et al.

Regarding claims 87-88, Roffman et al discloses an intraocular lens as shown above, but does not specifically disclose that the lens is made of acrylate. Chipman et al teaches of an intraocular lens (Column 1, line 60-Column 2, line 3, wherein the lens is an intraocular lens) made of acrylate for the purpose of providing a lens minimizing interfacial reflection and to provide the lens with the necessary refractive index (Column 5, lines 33-59). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the intraocular lens of Roffman et al to be made of acrylate since Chipman et al teaches of an intraocular lens made of acrylate for the purpose of providing a lens minimizing interfacial reflection and to provide the lens with the necessary refractive index.

Response to Arguments

Applicant's arguments filed February 24, 2005 have been fully considered but they are not persuasive. Specifically, applicant argues that the Roffman reference discloses that the intraocular lens replaces the natural lens, rather than being used with the lens in the capsular bag of the eye. However, the section of the Roffman reference referred to is in the background section of the reference (Column 1, lines 19-21) and is not referring to the use of intraocular lenses of the Roffman reference. Roffman does disclose that measurements of aberration of both the front and back lens surfaces are measured and an aspheric intraocular lens is place on one of

these surfaces, therefore using the lens in the capsular bag of the eye, rather than replacing the natural lens (Column 5, lines 6-17).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica T Stultz whose telephone number is (571) 272-2339. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica Stultz
Patent Examiner
AU 2873
May 4, 2005

JORDAN SCHWARTZ
PRIMARY EXAMINER